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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,246	07/24/2003	Christopher J. Elliott	10123/00601	1009
7590 Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038				
EXAMINER				
HOUSTON, ELIZABETH				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
09/11/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/626,246

Applicant(s)

ELLIOTT, CHRISTOPHER J.

Examiner

ELIZABETH HOUSTON

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-12 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-12 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 08/18/09 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1, 2, 5-10, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki (USPN 5, 980, 514) in view of Dormandy JR (US 5,382,260)**

3. Kupiecki discloses an embolic coil comprising an elongated core element (Fig 8, 204) formed of a shape memory material, nitinol, (Col 14, line 16) treated to define a memorized secondary coil shape; and an elongated outer element (202) wound around

the elongated core element to define a primary coil shape that is substantially a cylindrical coil of the embolic coil and formed of platinum (Col 14, line 18). It is inherent that the shape memory material, of which the elongated core element is formed, is in an austenitic phase at an operation temperature of the embolic coil. The memorized shape of the elongated core is a coil or spiral (Fig. 8). The secondary coil has a secondary coil memorized shape, wherein, when heated to a temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape (Col 14, lines 33-35).

4. Kupiecki does not disclose that the coil has fibers. However Dormandy discloses an embolic coil comprising polymeric fibers (22), that are looped through the turns of the coils (Figs 2-4; C3:L39-60) such that they are gripped between adjacent coil of the primary coil and held in place therebetween by friction (C3:L58-60). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the fibers into the coil in order to increase the diameter of the coil and the surface area thereby increasing thrombogenicity.

5. Regarding claim 5, Kupiecki in view of Dormandy teaches an outer elongated element with a primary coil shape but is silent as to how the primary shape is formed. The claimed phrase "cold working" is being treated as a Product by Process limitation that is the primary shape of the outer elongated element is formed by cold working. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the

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product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

6. Thus, even though Kupiecki is silent to the process used to form the cut, it appears that the product disclosed by Kupiecki would be the same or similar as that claimed; especially since both applicant's product and the prior art product has an embolic coil with a core and an outer element and a primary and secondary shape.

7. Claims 5, 11, 12 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki in view of Dormandy in view of Ferrera (USPN 6,171,326).

8. Kupiecki in view of Dormandy discloses all the limitations of the instant invention substantially as claimed as stated above except for the elongated outer element comprising a platinum wire co-wound with a shape memory material as in claim 12, fiber retention grooves formed on the core element as in claim 11 or applying cold work to the outer element as in claim 5.

9. With respect to claim 12, Ferrera discloses an embolic coil that incorporates the use of a multi-stranded micro-cable comprising both shape memory strands and radiopaque strands that can be platinum (Figs. 5 and 6 and Col 6, line 47 – Col 7, line 42). The advantage of using a multi-stranded cable is the relative flexibility and

resistance to kinking compared to a single wire resulting in less trauma to surrounding tissue and ease of placement in small body cavities.

10. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of the multi-stranded micro cable into the embolic coil to result in a device where the elongated outer element comprises a platinum wire co-wound with a shape memory material wire in order to achieve the advantages stated above.

11. Regarding claims 11 and 27-29, the resultant combination of Ferrera's multi-stranded cable with the base device provides fiber retention grooves as claimed (Note the circumferential and spiral grooves formed in between each strand in Fig 4, as well as the circumferential and spiral groove formed by the wrapped cover (56) in Figs. 10a and 10b).

12. Alternatively, regarding claim 5, Ferrera teaches cold working as a way of shaping embolic coils (Col 3, line 63-64). As an alternative to the product by process rejection stated above, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of cold working since it is a known process in the art as disclosed by Ferrera. The inventions are analogous with each other and the instant invention and therefore the combination is proper. Therefore, even if "cold working" results in different structural characteristics of the end product than other methods, it still would have been *prima facie* obvious at the time the invention was made to use "cold working" as claimed since Ferrera teaches that "cold working" is recognized as a useful technique for forming embolic coil shapes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
9/10/09